

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

UNITED STATES OF AMERICA)	
ex rel. John King and Jane Doe, et al.)	
)	
Plaintiffs,)	
)	
vs.)	CIVIL ACTION NO. 06-2662
)	
SOLVAY S.A. et al.,)	
)	
Defendants.)	
_____)	

**STATEMENT OF INTEREST OF THE UNITED STATES IN RESPONSE TO THE
MOTION TO DISMISS OF DEFENDANTS SOLVAY S.A. ET AL.**

INTRODUCTION

Pursuant to 28 U.S.C. § 517, the United States submits this Statement of Interest to assist the Court in considering one of the issues presented in this case: whether claims submitted to state Medicaid agencies in violation of the Anti-Kickback Statute are false within the meaning of the False Claims Act, 31 U.S.C. § 3729 et seq. In this case, two qui tam Relators assert, inter alia, that Abbott Products, Inc. (formerly known as Solvay Pharmaceuticals, Inc.) (SPI) paid kickbacks to induce physicians to write prescriptions for three drugs, AndgroGel, Aceon, and Luvox, in violation of the Anti-Kickback Statute. As a result, the Relators assert, the claims that SPI caused to be filed were false because kickback-tainted claims are per se ineligible for reimbursement under government health programs.

The United States has a substantial interest in the proper interpretation of the False Claims Act, which also serves as the model for many similar state anti-fraud statutes, because it is the government's primary tool to combat fraud and recover losses from fraud in federal

contracts and programs. The United States has an especially strong interest in the proper application of the FCA to claims for reimbursement for drugs prescribed because of kickbacks; as Congress has made clear, kickbacks to medical care providers corrupt medical judgment, undermine the integrity of government health insurance programs, and increase the costs of healthcare nationwide. Specifically, kickbacks create powerful incentives for physicians to prescribe inappropriate drugs, thereby increasing costs and potentially jeopardizing the health and safety of federal healthcare beneficiaries. Accordingly, although the United States has declined to intervene in this case, the United States files this Statement of Interest to provide the Court with its views on an important issue raised by SPI in its Motion to Dismiss.

Specifically, in its Motion to Dismiss, SPI erroneously argues that claims tainted by kickbacks can only be false under an “implied certification” theory of FCA liability. SPI further erroneously argues that, because the Fifth Circuit has not had occasion yet to endorse the “implied certification” theory, it would decline to do so in an appropriate case. Finally, SPI fails to recognize that the FCA prohibits SPI not only from submitting false claims directly, but also prohibits SPI from “causing” false claims to be submitted by engaging in a kickback scheme that results in the submission of false claims.

Because claims for reimbursement for drugs prescribed because of kickbacks are plainly false under the FCA even in the absence of any express or implied false certification, there is no need for this Court to determine whether the Relators’ Complaint states a claim under an express or implied false certification theory. However, in the event the Court reaches these issues, the United States files this Statement of Interest to clarify the relationship between the AKS and the FCA and the proper application of both the express and implied false certification theories of liability to that relationship.

BACKGROUND

I. STATUTORY SCHEME

A. Medicare and Medicaid

Medicare, established in 1965 by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., is a federally subsidized health insurance program for the elderly and certain disabled people. See 42 U.S.C. §§1395c, 1395d. To participate in Medicare, medical providers must first sign enrollment agreements. These agreements require participants to sign a Certification Statement, in which they attest that they understand that “payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with . . . the Federal anti-kickback statute.” Medicare Enrollment Application at 25 (Attachment A). Moreover, in signing this Certification Statement, Medicare participants agree that they are “meeting and maintaining” these Medicare requirements.

Medicaid is a cooperative federal-state public assistance program established by Title XIX of the Social Security Act, 42 U.S.C. 1396-1396v, under which federal matching funds are available to states that elect to pay for all or part of specified care and services furnished to needy individuals. See 42 U.S.C. § 1396; Harris v. McRae, 448 U.S. 297, 301 (1980). To participate in Medicaid, all medical providers must sign Medicaid enrollment agreements, which vary slightly from state to state, but generally certify that the provider will comply with all applicable federal and state laws and regulations.

For example, by signing the State of Texas Medicaid Provider Enrollment Application, a “Provider acknowledges and certifies” that it understands that “concealment of a material fact, or pertinent omissions may constitute fraud and may be prosecuted under applicable federal and state law.” Texas Medicaid Provider Enrollment Application (Attachment B) at 6.5. The

applicant further “acknowledges and certifies” that it understands that “any falsification, omission, or misrepresentation in connection with . . . claims filed may result in all paid services declared as an overpayment and subject to recoupment.” Id. The applicant further certifies that it will comply with the requirements of the enrollment agreement, including: “federal laws and regulations relating to fraud, abuse and waste in health care and the Medicaid program.” Id. at 6.2, 6.5. The Texas Medicaid enrollment agreement requires signatories to notify the State of Texas if it falls out of compliance with any of its obligations. Id.

B. The Anti-kickback Statute

The Anti-Kickback Statute (AKS) prohibits any person from knowingly offering to pay any remuneration to another person to induce the purchase, order, or recommendation of any good or item “for which payment may be made in whole or in part under a Federal health care program.” 42 U.S.C. § 1320a-7b(b). In addition to criminal penalties, violations of the AKS may result in civil monetary penalties and exclusion from participation in federal health care programs. 42 U.S.C. 1320a-7a(a)(7).

These substantial penalties reflect the significance of the prohibition against kickbacks as a critical tool in the fight against health care fraud. *See* H. Rep. 95-393, 95th Con., 1st Sess. at 44, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3047 (explaining that fraud in federal health care programs “cheats taxpayers who must ultimately bear the financial burden of misuse of funds in any government-sponsored program.”). Indeed, as part of the comprehensive health care reform legislation enacted in 2010, Congress amended the AKS, codifying the long-standing rule that “a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim” for the purposes of the FCA. Patient Protection and Affordable Care Act of

2010 (PPACA), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)).

C. The False Claims Act

The False Claims Act imposes civil liability when a person “knowingly presents, or causes to be presented” to the government “a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1), or “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” 31 U.S.C. § 3729(a)(2).¹ The Attorney General may bring a civil action if he finds that a person has committed an FCA violation. 31 U.S.C. § 3730(a). Alternatively, a private person, known as a relator, may bring a qui tam action “for the person and for the United States Government. 31 U.S.C. § 3730(b)(1). If a qui tam action results in the recovery of damages or civil penalties, the award is divided between the government and the relator. 31 U.S.C. § 3730(d).

II. FACTUAL ALLEGATIONS

In this declined qui tam, the Relators, John King and Jane Doe, allege fraud against Medicare, Medicaid, and other federal healthcare programs as a result of off-label marketing and kickback schemes relating to three drugs: Luvox, Aceon, and AndroGel. Relators contend that in order to expand and maintain its market share for these drugs, SPI marketed uses that had not been approved by the Food and Drug Administration and offered kickbacks to physicians in exchange for writing prescriptions for these drugs. 4th Amended Complaint at ¶ 1. With respect to the kickback allegations, specifically, Relators contend that SPI rewarded physicians for writing prescriptions of its drugs with cash, resort weekends, and gifts. *Id.* at ¶ 296. Relators allege that SPI offered doctors cash for performing small tasks, like filling out paperwork,

¹ This section of the FCA was amended in 2009 by the Fraud Enforcement and Recovery Act (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (2009). Although the amendments to § (a)(2) were made retroactive, the analysis would be the same under either version of the FCA.

speaking to small audiences, or attending workshops, all of which were thinly veiled rewards for doctors who wrote prescriptions for SPI's drugs. *Id.* at ¶¶ 299, 301, 305.

DISCUSSION

CLAIMS SUBMITTED TO FEDERAL HEALTHCARE PROGRAMS IN VIOLATION OF THE ANTI-KICKBACK ACT ARE FALSE WITHIN THE MEANING OF THE FALSE CLAIMS ACT.

In its Motion to Dismiss, SPI argues that the alleged claims tainted by kickbacks can only be false under an “implied certification” theory of FCA liability. Because the Fifth Circuit has not had occasion yet to endorse the “implied certification” theory, SPI concludes that the implied certification theory is not available in this Circuit. Finally, SPI argues that it cannot be held liable under the FCA for engaging in a kickback scheme that results in the submission of false claims because it was not paid directly for claims it caused to be submitted to state Medicaid agencies. Each of these arguments is incorrect.

The False Claims Act imposes civil liability where a person “knowingly presents, or causes to be presented” to the government “a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1), or “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” 31 U.S.C. § 3729(a)(2). As the Supreme Court has explained, in enacting the FCA, “Congress wrote expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the Government.” *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003). Recognizing that the “FCA is the government’s primary litigation tool for recovering losses resulting from fraud,” *United States ex rel. Steury v. Cardinal Health*, 625 F.3d 262, 267 (5th Cir. 2010), the Fifth Circuit has held that the “FCA reaches beyond ‘claims’ which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of

money.” United States ex rel. Riley v. St Luke’s Episcopal Hospital, 355 F.3d 370, 379 (5th Cir. 2004).

In determining whether a claim is “false” within the meaning of the FCA, the critical question is not whether the person who actually submits the claim knows that it is false, but whether a material condition of payment was not satisfied. United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 902 (5th Cir. 1997) (“where the government has conditioned payment of a claim upon a claimant’s certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation.”).

A. Claims for Reimbursement Tainted by Kickbacks Violate a Fundamental Condition of Payment Under Federal Health Care Programs and are Therefore False Even Absent Any Express or Implied Certification.

Compliance with the AKS is a fundamental condition of payment under all federal health care programs. The offer or receipt of a kickback for the provision of medical services reimbursed by federal funds is a felony. 42 U.S.C. § 1320a-7b(b). By making it a felony for a person to offer or receive kickbacks for services reimbursed by federal funds, Congress made clear that compliance with the AKS is central to federal reimbursement of medical care. Were this not the case, the federal government would be in the position of funding illegal behavior after the fact. United States ex rel. Pogue v. Diabetes Treatment Centers of America, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) (noting the “absurdity” of the argument that claim tainted by kickbacks could be both illegal and reimbursable under a federal health care program); see also United States ex rel. Bidani v. Lewis, 264 F. Supp. 2d 612, 616 (N.D. Ill. 2003).

The rationale for non-payment of kickback-tainted claims is clear: when a claim is tainted by a kickback, the government has no assurance that the medical services, including drugs

prescribed, were “reasonable and necessary” for the treatment of the patient. The AKS is thus the embodiment of Congress’s belief that the judgment of a physician who receives something of value in return for the referral of medical procedures is per se tainted by the financial incentive being offered. See, e.g., Kickbacks Among Medicaid Providers, Report by the Senate Special Committee on Aging, S. REP. NO. 95-320, at 2 (1977) (observing that kickbacks “undermine the quality of services which are offered since operators become more concerned with rebates than with care”). Accord GAO, Vulnerable Payers lose Billions to Fraud and Abuse, May 1992, at 9 (“Because kickbacks constitute payments to induce services, they increase insurers’ vulnerability to claims for unnecessary services.”). The basic premise underlying the AKS is Congress’s determination that money corrupts health care decisions.

In accord with Congress’s intent, numerous courts have recognized that claims for payment for services induced by kickbacks are false claims under the FCA. See United States ex rel. Conner v. Salina Regional Health Ctr., 543 F.3d 1211, 1223 n.8 (10th Cir. 2008); United States ex rel. McNutt v. Haleyville Medical Supplies, 423 F.3d 1256, 1259-60 (11th Cir. 2005); United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 243 (3d Cir. 2004); United States ex rel. Jamison v. McKesson, 2009 WL 3176168 at *11 (N. D. Miss. 2009); United States v. Rogan, 459 F. Supp. 2d, 717 (N.D. Ill. 2006), aff’d 517 F.3d 449 (7th Cir. 2008). While some of these decisions have focused on “false certifications” made by defendants, the presence of such certifications is not necessary to render payment for goods or services tainted by kickbacks false. What makes a claim “false” is its ineligibility for payment - a condition that all claims tainted by kickbacks satisfy. While other elements are also necessary for liability under the FCA (e.g. knowledge and materiality), the question of “falsity” turns on whether the claimant is eligible for payment under the federal program at issue. United States ex rel. Hendow v. University of

Phoenix, 461 F.3d 1166, 1174 (9th Cir. 2006). As the legislative history accompanying the 1986 FCA Amendments makes clear, “claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program.” Sen. Rep. No. 345, 99th Cong. 2d Sess., at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274.

As a result, although one way in which a claim may be “false” under the FCA is where it rests on a false certification of compliance with a condition of payment (either express or implied), it is not necessary to examine any “certifications” made in connection with claims for goods or services that do not conform to the government’s stated criteria for payment. When the government has made clear that payment is conditioned on certain requirements, a claim for goods or services that do not comply with those criteria is “false” regardless of what certifications are made in connection with that claim. Covington v. Sisters of Third Order of St. Dominic, 61 F.3d 909 (9th Cir. 1995) (defendant liable under the False Claims Act when defendant received reimbursement to which it was not entitled due to government error because “mere receipt of government funds known to have been paid my mistake is a false claim”). Similarly, where a defendant knowingly causes a third party, like a pharmacy, to present an ineligible claim for payment to the government, the critical question is not what the third party knew or certified at the time. What matters instead is whether the defendant knew the claim was “false” - that is, that a material condition of payment was not satisfied - and caused its submission to the government, either directly or through a third party. See Schmidt, 386 F.3d at 243-44.

If there were any serious doubt that claims tainted by kickbacks are “false” within the meaning of the FCA, Congress recently confirmed this point. In the PPACA, Congress amended the AKS to provide that a “claim that includes items or services resulting from a violation of this

section constitutes a false or fraudulent claim” within the meaning of the FCA. PPACA § 6402(f). The amendment clarifies that all claims for services that were tainted by the payment of a kickback are false claims within the meaning of the FCA, regardless of what entity ultimately submitted the claims for payments and regardless of whether that entity expressly certified compliance with the AKS. See 155 Cong. Rec. S10854 (Statement of Sen. Leahy) (explaining that the amendment was intended “to ensure that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil action under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves.”); 155 Cong. Rec. S10853 (Statement of Sen. Kaufman) (same).

SPI argues that the fact that the PPACA specifically makes kickback-tainted claims false within the meaning of the FCA means that kickback-tainted claims filed prior to its enactment are not “false” for FCA purposes. This argument wrongly assumes the amendment to PPACA intended a wholesale change in the law on this point rather than a confirmation of the longstanding relationship between the FCA and AKA. The PPACA amendment reflects the basic principle, already established in the 1986 FCA amendments, that “claims may be false even though services are provided as claimed if, for example, the claimant is ineligible to participate in the program.” Sen. Rep. No. 345, 99th Cong. 2d Sess., at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274. Indeed, in the legislative history accompanying the PPACA amendments, Congress made clear that it was clarifying the relationship between the AKS and the FCA. 155 Cong. Rec. S10854 (Statement of Sen. Leahy). By specifying that claims tainted by kickbacks are “false” under the FCA, the PPACA amendment embodies the principle expressed in 1986 and is persuasive evidence of how claims made prior to the effective date of the new legislation should be treated. See Loving v. United States, 517 U.S. 748, 770 (1996) (“Subsequent legislation

clarifying the intent of an earlier statute is entitled to great weight in statutory construction.”); Bates v. United States, 522 U.S. 23, 32 (1997) (rejecting argument that clarifying amendments demonstrated that prior version of statute did not cover conduct in question).

Moreover, Congress’ intention in enacting the PPACA amendment becomes clear in light of the many Courts of Appeals decisions that expressly found that a violation of the AKS makes a claim false within the meaning of the FCA prior to the PPACA’s enactment. See, e.g., Conner, 543 F.3d at 1223 n.8; McNutt, 423 F.3d at 1259-60; Schmidt, 386 F.3d at 243; Rogan, 459 F. Supp. 2d, 717 (N.D. Ill. 2006), aff’d 517 F.3d 449. It would be singularly perverse to hold that Congress’ approval of these decisions vitiates their force retroactively. See Faragher v. City of Boca Raton, 524 U.S. 775, 792 (1995) (Congress intends to adopt judicial opinions when it amends a statute and does not modify these opinions).

B. Express False Certification of Compliance with the AKS is a False Claim under the FCA.

Because claims tainted by kickbacks are false within the meaning of the FCA, it is not necessary for the Court to decide whether violating the AKS is also either an “express” or “implied” false certification – these are merely specific examples of ways in which claims can be false. United States ex rel. Willard v. Humana Health Plan of Texas, Inc., 336 F.3d 375, 382 (5th Cir. 2003) (“Implied certification amounts to nothing more than an alternative expression of the well-accepted idea that billing the government for something not delivered may constitute a false claim.”). Nevertheless, SPI’s argument that the Relators failed to state a claim under an express certification theory ignores the explicit language of the provider agreements, which are express certifications of compliance with the AKS. Because the FCA’s reach extends to entities that “cause” false claims to be submitted, an FCA action lies against an entity that causes a

provider to submit claims tainted by kickbacks because providers expressly certify compliance with the AKS.

As noted, to participate in Medicare, medical providers must sign enrollment agreements in which providers certify that they understand that “payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with . . . the Federal anti-kickback statute.” Medicare Enrollment Application at 25. Similarly, to participate in Medicaid, all medical providers must sign Medicaid enrollment agreements, which vary slightly from state to state, but generally certify that the provider will comply with federal laws and regulations related to fraud and abuse. For example, in Texas, a “Provider acknowledges and certifies” that it understands that “concealment of a material fact, or pertinent omissions may constitute fraud and may be prosecuted under applicable federal and state law.” Texas Medicaid Provider Enrollment Application at 6.5. The applicant further “acknowledges and certifies” that it understands that “any falsification, omission, or misrepresentation in connection with . . . claims filed may result in all paid services declared as an overpayment and subject to recoupment.” *Id.* The applicant further certifies that it will comply with the requirements of the enrollment agreement, including: “federal laws and regulations relating to fraud, abuse and waste in health care and the Medicaid program.” *Id.* at 6.2, 6.5.

It is beyond doubt that compliance with the AKS is at the heart of the Medicaid providers’ certifications to comply with the federal laws related to federal healthcare program fraud and abuse. Centrally, the AKS was enacted as part of a comprehensive program to eliminate fraud on Medicare and Medicaid. United States v. Greber, 760 F.2d 68, 70-71 (3d Cir. 1985). Indeed, even the title of the law enacting the AKS itself, “An Act to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the

Medicare and Medicaid programs” demonstrates the fundamental connection between the AKS and the government’s anti-fraud efforts. Pub. L. 95-142, 91 Stat. 1183 (1977). In addition, in both the Medicare and Texas Medicaid enrollment agreements, participants agree not only that they are in compliance with the AKS at the time of enrollment, but also that they will remain in compliance, Medicare Enrollment Application at 25, and will notify the appropriate government official if they fall out of compliance, Texas Medicaid Enrollment Application at 6.5.

Contrary to SPI’s assertions, these statements are express certifications of compliance with the AKS within the meaning of the FCA. By any definition, a “certification” includes signing a document that purports to be a certification, as do the Medicare and Texas Medicaid enrollment applications. E.g. United States ex rel. Lemon v. Envirocare of Utah, 614 F.3d 1163, 1168 (10th Cir. 2010). As courts have universally recognized, a payee’s “certification” “can be any false statement that relates to a claim.” Id. (citing United States ex rel. Hendow v. University of Phoenix, 461 F.3d 1166, 1172 (9th Cir. 2006) (“it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach.”)). As a result, the Relators have properly alleged that the certifications submitted by Medicare and Medicaid participants constitute express certification of compliance with the AKS.

SPI’s misapprehension of the law is most obvious in its assertion that “for a pharmacy’s certification to be false, the pharmacy would have to be certifying that SPI had complied with the AKS when in fact, it knew that SPI had violated the AKS.” Motion to Dismiss at 24 n.12. This is not correct. SPI ignores the plain language of the FCA, which provides that a person can be liable under the FCA for causing a false claim to be filed. 31 U.S.C. § 3729; United States v. Bornstein, 423 U.S. 303, 313 (1976). If SPI was indeed offering kickbacks in violation of the AKS, then the certifications and claims submitted by pharmacies as a result of the AKS

violations were caused by SPI to be false. The knowledge of any pharmacies who submitted the claims is irrelevant to SPI's liability. As long as SPI had the requisite knowledge, by causing the submission of false claims, it has violated the FCA.² Bornstein, 423 U.S. at 313 (a defendant can "cause" a false claim to be submitted even though the entity that actually submits the false claim is innocent of wrongdoing and therefore not liable under the FCA); Schmidt, 386 F.3d at 243-44 ("the knowledge and conduct of the defendant were what mattered and the outcome did not turn on whether the actual presenters were 'duped' or participated in the fraudulent scheme"); United States ex rel. Rost v. Pfizer, Inc., --F. Supp. 2d. --, 2010 WL 3554719 at *8 (D. Mass. 2010) ("The Supreme Court has long held that a person may be liable under the FCA for causing an innocent third party to submit a false claim to the government without knowing it is false.")

C. Implied False Certification of Compliance with the AKS is a False Claim under the FCA.

Because claims tainted by kickbacks are false within the meaning of the FCA, and because, in any event, submission of a claim tainted by kickbacks is a violation of an express certification of compliance with the AKS in the provider agreements, it is not necessary for the Court to decide whether it will recognize an "implied" false certification theory. However, if the Court does reach this issue, it should recognize a theory of implied false certification. First, the implied false certification theory, which prohibits a government payee from withholding material information from the United States about its noncompliance with payment conditions, is consistent with the plain language of the FCA. Section 3729(a)(1)(A) (formerly § 3729(a)(1)) prohibits the submission of a false claim and, importantly, does not require the submission of a false statement. 31 U.S.C. §3729. Rather, by prohibiting the submission of a false claim even in

² If the pharmacy knew that it was filing a false claim, then the pharmacy would be liable under the FCA. There are no allegations that, in fact, a pharmacy knew that it was filing a false claim.

the absence of a false statement, the language of the FCA is consistent with the logic of the implied false certification theory, in which a payee merely withholds material information. United States v. Science Applications International Corp., 626 F.3d 1257, 1266-67 (D.C. Cir. 2010). Second, the implied false certification theory is consistent with the legislative history of the FCA, in which Congress made clear that the FCA reaches a person who claims government funds under a federal program as long as “the claimant is ineligible to participate in the program.” Sen. Rep. No. 345, 99th Cong. 2d Sess., at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5274. By failing to comply with the AKS, a drug manufacturer would be “ineligible to participate” in the Medicare and Medicaid programs and, as a result, ineligible to receive funds under those programs. Third, SPI notes that the Fifth Circuit has not yet specifically adopted the implied false certification theory. Although the Fifth Circuit never has had occasion to hold whether an FCA violation can be predicated on an implied false certification, Steury, 625 F.3d at 268, neither has the Fifth Circuit rejected the implied false certification theory. Indeed, at least one district court in the Fifth Circuit has held that “failure to comply with the kickback laws is, in and of itself, a false statement to the government.” Jamison, 2009 WL 3176168 at *11 (citing United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc., 238 F. Supp. 2d 258, 264 (D.D.C. 2002)).

It is no doubt for all of these reasons that a majority of the Courts of Appeals have already recognized the implied false certification theory: the Courts of Appeals for the Second, Sixth, Ninth, Tenth, Eleventh, and D.C. Circuits, as well as the Court of Federal Claims, have all expressly adopted the false implied certification as a viable theory of liability under the FCA. SAIC, 626 F.3d 1266-67; United States ex rel. Ebeid v. Lungwitz, 616 F.3d 993, 996 (9th Cir. 2010); Conner, 543 F.3d at 1217-18; McNutt, 423 F.3d 1259-60; United States ex rel. Augustine

v. Century Health Services, 289 F.3d 409, 415-16 (6th Cir. 2002); Mikes v. Straus, 274 F.3d 687, 700 (2d Cir. 2001); Ab-Tech Construction, Inc. v. United States, 31 Fed. Cl. 429 (1994) aff'd 57 F.3d 1084 (Fed. Cir. 1995). See also In re: Industry Average Wholesale Price Litigation, 491 F. Supp. 2d 12, 17-18 (D. Mass. 2007) (“failure to comply with the kickback laws, therefore, is in and of itself, a false statement to the government. . . . Thus, the government can state a claim under the FCA for an antecedent violation of the Anti-Kickback Statute for claims submitted through the Medicare program.”).

Most recently, in SAIC the D.C. Circuit considered and adopted the implied false certification theory of FCA liability, rejecting the same arguments against liability that SPI asserts in this case. According to the SAIC defendant, “a claim can be false under the implied certification theory only if the government contractor violates legal requirements that are expressly designated as preconditions to payment.” SAIC, 626 F.3d at 1268. The D.C. Circuit rejected this cramped reading of the FCA, holding that “nothing in the statute’s language specifically requires such a rule, and we fear that adopting one would foreclose FCA liability in situations that Congress intended to fall within the Act’s scope.” Id. The court went on to hold that the plaintiff need only show that the payee “withheld information about its noncompliance with material” conditions of payment. Id. at 1269. The court further went on to specifically reject SAIC’s argument that the plaintiff must show the “existence of express contractual language specifically linking compliance to eligibility for payment.” Id. For the same reasons, this Court should reject SPI’s argument that an implied false certification requires specific contractual, statutory, or regulatory language linking compliance with the AKS to eligibility for payment under Medicare or Medicaid. Recognizing an implied false certification theory under the FCA puts into effect Congress’s intention in enacting the FCA, which was “to reach all types

of fraud, without qualification, that might result in financial loss to the government.” Chandler, 538 U.S. at 129 (citing United States v. Neifert-White Co., 390 U.S. 228, 232 (1968) (emphasis added)).

CONCLUSION

Claims for reimbursement for drugs presented by a pharmacy to a federal healthcare program are false within the meaning of the FCA when these claims are tainted by kickbacks offered to the physicians who prescribed these drugs. Because claims tainted by kickbacks are false, there is no need for this Court to reach the issue of whether the Relators’ Complaint states a claim under an express or implied false certification theory. However, if the Court reaches these issues, it should hold that a violation of the AKS can serve as a false certification under either the express or implied theories of false certification liability for the purposes of the FCA.

Dated: February 7, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Statement of Interest was served this 7th day of February, 2011, electronically, on: all CM/ECF participants in the case.

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